

### **REMARKS/ARGUMENTS**

Applicants have carefully reviewed the Office Action mailed on January 24, 2007. Applicants respectfully traverse all objections, rejections, and assertions made by the Examiner. With this amendment, a number of the claims have been amended, as indicated above. Support for these amendments can be found in the specification and drawings as originally filed, and no new matter has been added. Claims 1-4, 6-8, 10, 13-14, 18-20, 25, 27, 53, 55, 58-59, and 76-87 remain pending.

### **Inventorship and Corrected Filing Receipt**

A request to correct inventorship under 37 C.F.R. §1.48(c) was filed on December 17, 2004. With that filing, Applicants additionally requested the issuance of a corrected filing receipt reflecting the change of inventorship. Applicants have not yet received an indication that the inventorship has been corrected, and have not yet received a corrected filing receipt reflecting the change of inventorship. Applicants respectfully request that these be issued in due course.

### **Drawings**

The drawings were objected to. The Examiner indicated that Figure 4 in the drawings submitted on January 16, 2006 has not been labeled in the drawings. We believe that the Examiner is referring to the set of drawings submitted January 13, 2004 (received January 16, 2004). Please note that on February 13, 2004, Applicants filed an electronic submission for Pre-Grant Publication. This submission included formal drawings that corrected the deficiency in Figure 4 identified by the Examiner. Consequently, Applicants respectfully submit that the drawings attached to that submission are in compliance with 37 C.F.R. §1.121(d) and overcome the objection.

In the next communication from the office, Applicants respectfully request that the Examiner indicate whether or not the set of formal drawings filed with the February 13, 2004 submission is accepted.

**Claim Rejections under 35 U.S.C §103**

Claims 1-4, 6-8, 10, 14, 19, 20, 25, 27, 53, 55, 58, 59, and 76-87 are rejected under 35 U.S.C. §103(a) as being anticipated by Jacobsen et al. in U.S. Patent No. 6,579,246 in view of Shiber in U.S. Patent No. 5,135,531. Applicants respectfully traverse this rejection.

Regarding claims 1-4, 6, and 76-78, claim 1 as amended recites as follows:

1. (Currently amended) A medical device for navigation through anatomy, the medical device comprising:

an elongate body having a proximal end, a distal end, and a longitudinal axis extending at least from the proximal end to the distal end; and

a helical first radiopaque marker coil formed from a wire having a substantially non-circular cross section and made from a radiopaque material; and

said non-circular cross section having a greater dimension in the radial direction than in the axial direction.

In essence, claim 1 now more clearly indicates that the claimed coil is a radiopaque marker coil, which is made from a wire made of a radiopaque material, and that the radiopaque marker coil has a non-circular cross section with a greater dimension in the radial direction than in the axial direction.

It is apparent that the Examiner is asserting that it would have been obvious to modify the guidewire construction disclosed in Jacobsen et al. by modifying the distal marker coil (e.g. 538) in Jacobsen et al. in accordance with the auger-like “casing” in the form of a helical wire 93 made of two flat layers 64 and 66 as depicted in Figure 11 of Shiber. We respectfully disagree.

MPEP §2143 states that to establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a

reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

As indicated in MPEP §2143.01, “[i]n determining the propriety of the Patent Office case for obviousness in the first instance, it is necessary to ascertain whether or not the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the reference before him to make the proposed substitution, combination, or other modification.” (citations omitted). “The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.” MPEP §2143.01 III (citations omitted) (second emphasis added). A statement that modifications of the prior art to meet the claimed invention would have been “well within the ordinary skill of the art at the time the claimed invention was made’ because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a prima facie case of obviousness without some objective reason to combine the teachings of the references.” MPEP §2143.01 IV (emphasis added)(citations omitted). Additionally, the teaching or suggestion to make the claimed combination must be found in the prior art, not in applicant’s disclosure. MPEP §2143 (citation omitted).

Applicants respectfully submit that there is no apparent suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify Jacobsen et al. reference in view of the Shiber reference to arrive at the claimed invention. As indicated by the Examiner, Jacobsen et al. reference fails to teach or suggests that the radiopaque marker coil therein could be made from a wire having a non-circular cross section having a greater dimension in the radial direction than in the axial direction. Shiber similarly fails to provide any suggestion or motivation for changing the configuration of the radiopaque marker coil in Jacobsen et al. to arrive at the claimed invention.

Instead, Shiber appears to be directed to an atherectomy system for coring, ingesting and removing an obstruction material from within a patients vessel. The helical wire can apparently be inserted into a tight obstruction by rotating it, threading it into the obstruction. In the process of threading, the helical wire apparently pulls itself across the obstruction and

anchors itself in the obstruction material. (see, e.g. Col. 4, ln. 68 through Col. 5, Ln. 4.) Once the helical wire is in place, it apparently reinforces the obstruction material and firmly holds it in place, preparatory to coring it. (see, e.g. Col. 9, lines 34-36). The flexible catheter including the coring means is then advanced over the helical wire (i.e. “casing”), thereby coring and ingesting the obstruction material. (see, e.g. Col. 10, lines 24-49). In the embodiment shown in Figure 11, and referenced by the Examiner, the casing is in the form of a helical wire 93 made of two flat layers 64 and 66. However, throughout the specification in Shiber, it appears that the helical wire, or “casing” is configured to function as an auger-like member for threading into an obstruction. This has nothing to do with radiopaque marker coils, nor does it suggest that the configuration illustrated in Figure 11 of Shiber would be appropriate for use as a radiopaque marker coil. Thus, the references fail to provide any motivation or suggestion to modify the radiopaque marker coil in Jacobsen et al. reference in view of the Shiber reference.

Applicants respectfully submit that one of ordinary skill in the relevant art, having these two references before him, would not be motivated to make the modification proposed by the Examiner. There is nothing apparent either in the references themselves, or otherwise in the prior art, that suggests the desirability of the proposed combination and/or modification. For example, even with the teachings of Shiber in hand, it seems unlikely that one of skill in the art would consider the shape of the auger-like helical wire structure in Shiber a reasonable alternative for the radiopaque marker coil in Jacobsen et al. – nothing seem to suggest that such a construction would be desirable, as is required. There is no apparent objective reason to combine the teachings of the references and/or make the proposed modification.

Only when Applicants’ specification is considered, using reconstructive hindsight, would the motivation for such a combination and/or modification seem remotely feasible. For example, the Applicant’s specification indicates that a radiopaque marker coil that has a non-circular cross section with a greater dimension in the radial direction than in the axial direction may be desirable to provide the radiopaque marker coil with a high degree of bending flexibility, greater radiopacity, or both. (see, e.g. paragraphs 0066 and 0067 of the publication of the present application (2004/0181174)). However, such reconstructive hindsight in view of the applicants specification is impermissible, and Applicants respectfully

submit that there is no such suggestion or motivation in the prior art to combine the teachings of the references and/or make the proposed modification. As such, Applicants respectfully submit that a *prima facie* case of obviousness has not been properly established, and respectfully request withdrawal of the rejection of claims 1-4, 6, and 76-78 in due course.

Regarding claims 7-8, 10, 14, 19, 20, 25, 27, 53, 55, 58, 59, and 79-87, independent claims 7, 25, and 53 all now recite in part, that the recited radiopaque marker coil is formed from, or made of, a radiopaque wire having a substantially non-circular cross section that has a greater dimension in the radial direction than in the axial direction. For reasons similar to those set forth above in relation to claim 1, Applicants respectfully submit that there is no apparent suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify Jacobsen et al. reference in view of the Shiber reference to arrive at the invention set forth in these claims. Applicants respectfully submit that for at least this reason, and because these claims include additional elements to distinguish them further from the cited art, a *prima facie* case of obviousness has not been established for these claims. Consequently, the rejection of these claims should, likewise, be withdrawn.

In addition, on page 5 of the Office Action, the Examiner further indicated, making reference to claims 76-87, that “one of ordinary skill in the art would recognize Shiber implicitly teaches a coil that is created from a trapezoidal cross-sectioned wire and when the coil is formed, the trapezoidal shape becomes a rectangular cross section.” Applicants do not believe that the Examiner has adequately demonstrated that one of ordinary skill in the art would “implicitly” recognize this from the teachings of Shiber – such a teaching does not appear to be either explicitly or inherently disclosed therein. Should the Examiner insist that this feature is “implicitly” taught in Shiber (or that this characteristic necessarily flows from the teachings thereof), Applicants respectfully request that the Examiner provide a reference to support this position, or provide a basis in fact and/or technical reasoning to reasonably support the determination that the missing subject matter necessarily flows from the teachings of Shiber.

Claims 13 is rejected under 35 U.S.C. 103(a) as being unpatented over Jacobsen et al. and Shiber as applied to claim 7 above, and further in view of Lui in U.S. Patent Application Publication No. 2002/0010475. As indicated above, claim 7 is believed to be patentable over Jacobsen et al. and Shiber at least because there is no motivation to combine the references to arrive at the claimed invention. Lui does not overcome this deficiency. Accordingly, Applicants respectfully submit that claim 7 is patentable over Jacobsen et al., Shiber, and Lui. Because claim 13 depends from patentable claim 7, it is patentable for the same reasons and because it adds significant elements to distinguish it further from the art.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatented over Jacobsen et al. and Shiber as applied to claim 7 above, and further in view of Levine et al. in U.S. Patent Application Publication No. 2003/0009157. As indicated above, claim 7 is believed to be patentable over Jacobsen et al. and Shiber at least because there is no motivation to combine the references to arrive at the claimed invention. Levine et al. does not overcome this deficiency. Accordingly, Applicants respectfully submit that claim 7 is patentable over Jacobsen et al., Shiber, and Levine et al. Because claim 18 depends from patentable claim 7, it is patentable for the same reasons and because it adds significant elements to distinguish it further from the art.

Claims 76 is rejected under 35 U.S.C. 103(a) as being unpatented over Jacobsen et al. and Shiber as applied to claim 1 above, and further in view of Tsuji et al. in U.S. Patent No. 5,181,668. As indicated above, claim 1 is believed to be patentable over Jacobsen et al. and Shiber at least because there is no motivation to combine these references to arrive at the claimed invention. Tsuji et al. does not overcome this deficiency. Accordingly, Applicants respectfully submit that claim 1 is patentable over Jacobsen et al., Shiber, and Tsuji et al. Because claim 76 depends from patentable claim 1, it is patentable for the same reasons and because it adds significant elements to distinguish it further from the art.

**Conclusion**

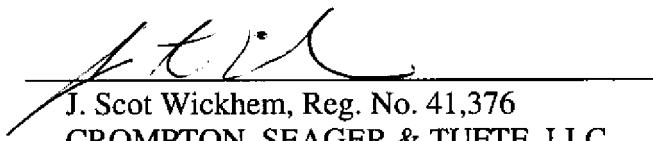
Reexamination and reconsideration are requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is also respectfully requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By their attorney,

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